§5.95 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act:

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[56 FR 6263, Feb. 15, 1991]

§5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to approve electronic reporting under §803.14 of this chapter.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to request the submission of additional information under §803.15 of this chapter.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under §803.19 of this chapter.

[60 FR 63607, Dec. 11, 1995]

§5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER[1]

IMMEDIATE OFFICE

Office of the Administrative Law Judge.
Office of Executive Operations.
Office of Equal Employment Opportunity and Civil Rights.
Office of Chief Counsel.
Office of Internal Affairs.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.